



CMI INSTRUCTION FOR USE

19-5072 REV D

Application :

Specialty instrumentation and sizers are designed to aid the surgeon in installation, assembly, and/or removal of surgical device. The surgical techniques for implantation of the device describe the proper application of specialty instrumentation and should be read and understood by the surgeon prior to use.

Warnings:

- Clean, not sterile, instruments and sizers must be sterilized prior to each use.
- Sizers are designed to aid in implant site preparation only. They must never be used as implants.
- The most common cause of instrument breakage is misuse. Specialty instrumentation should never be used for tasks it was not specifically designed to perform. Misuse of an instrument may result not only in damage to the instrument, but also trauma to the patient and operating room personnel.
- If not handled properly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgical gloves.
- If an instrument tip becomes bent, chipped, or otherwise damaged the instrument should be replaced or repaired before further use. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromised in the process, and the instrument may subsequently break during use.

Limited warranty:

Tornier, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser. Tornier, Inc. does not warrant the outcome of the surgical procedure.

Cleaning instructions:

The instrument sets are supplied non-sterile. It is the responsibility of the hospital to pre-disinfect, clean and sterilize the instruments before use, by using validated methods.

In order to preserve the optimum efficiency and safety of the instruments, the following instructions must be applied:

- The use of metallic brushes and other articles likely to damage the instruments must be avoided;

- Chemicals likely to damage the instruments, such as chlorine, must not be used.

Pre-disinfection and cleaning must be performed before sterilization. The pre-disinfection aims to reduce the microorganisms population and to make the subsequent cleaning easier.

- It is obtained by dipping the instruments, 15 minutes at least, in an alkaline deterging-decontaminating bactericidal and fungicidal solution containing didecyl ammonium chloride combined with proteolytic enzymes.
- The solution must not contain aldehyde, Tornier, Inc. recommends using ALKAZYME ® diluted at 0.5 %.
- The instruments must be carefully rinsed in order to avoid any problem of interference between the decontamination and cleaning solutions. The pre-disinfection solution should be change frequently (after each use) to avoid its saturation.

Cleaning allows the elimination of organic and mineral materials that still stick to the surface of the instrument.

- It must be performed by manual washing with a disinfecting bactericidal, fungicidal and virucidal solution like HEXANIOS ® solution by dipping the instruments 15 minutes at least.

Tornier, Inc. suggests using a soft and firm brush or ultrasonic bath in order to eliminate the visible stains.

Sterilization:

The recommended sterilization method is steam sterilization. The following sterilization cycles have been shown to produce a sterility assurance level of 10⁻⁶ when parts have been cleaned to the instructions above. Other similar steam cycles and cleaning procedures may be used but have not been evaluated. Sterilization qualification was performed using specific equipment and procedures. Use of cycles, equipment and procedures other than those listed should be qualified by the user. Do not exceed 300°F/149°C.

Wrapped Gravity Steam Sterilization 35 minutes minimum @ 270-275°F (133-135°C)

Unwrapped Pre-vacuum Steam Sterilization 12 minutes minimum @ 270-275°F (133-135°C)

For further information on the above cleaning and sterilization recommendations please contact Tornier, Inc.

Symbol	Meaning		Not Made with Natural Rubber Latex
	Catalog Number		Do Not Use if product is broken, damaged or open
	Lot Number		Non-Sterile
	Consult accompanying documents		Caution: Federal Law (USA) restricts this device to sale by or order of a physician
	Consult Instructions for Use		Manufacturer

